10A NCAC 14C .3702 INFORMATION REQUIRED OF APPLICANT

(a) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall use the Acute Care Facility/Medical Equipment application form.

(b) An applicant proposing to acquire a PET scanner, including a mobile PET scanner, shall provide the following information for each facility where the PET scanner will be operated:

(1) The projected number of procedures to be performed and the projected number of patients to be served for each of the first three years following completion of the proposed project. Projections shall be listed by clinical area (e.g., oncology, cardiology), and all methodologies and assumptions used in making the projections shall be provided.

(2) Documentation of arrangements made between the applicant and other providers to assure patients of the facility will have access to all of the following services:
- (A) nuclear medicine imaging services;
- (B) single photon emission computed tomography (including brain, bone, liver, gallium and thallium stress);
- (C) magnetic resonance imaging scans;
- (D) computerized tomography scans;
- (E) cardiac angiography;
- (F) cardiac ultrasound; and
- (G) neuroangiography;
- (H) radiation oncology;
- (I) medical oncology; and
- (J) surgical oncology.

(3) Documentation that the facility will:
- (A) establish the clinical PET unit, and any accompanying equipment used in the manufacture of positron-emitting radioisotopes, as a regional resource that will have no administrative, clinical or charge requirements that would impede physician referrals of patients for whom PET testing would be appropriate; and
- (B) provide scheduled hours of operation for the PET scanner of a minimum of 60 hours per week, except for mobile scanners.

(c) An applicant proposing to acquire a mobile PET scanner shall provide copies of letters of intent from and proposed contracts with all of the proposed host facilities at which the mobile PET scanner will be operated.

(d) An applicant proposing to acquire a mobile PET scanner shall demonstrate that each host facility offers or contracts with a hospital that offers comprehensive cancer services including radiation oncology, medical oncology, and surgical oncology.

(e) An applicant shall document that all equipment, supplies and pharmaceuticals proposed for the service have been certified for use by the U.S. Food and Drug Administration or will be used under an institutional review board whose membership is consistent with U.S. Department of Health and Human Services' regulations.

(f) An applicant shall document that each PET scanner and cyclotron shall be operated in a physical environment that conforms to federal standards, manufacturer's specifications, and licensing requirements. The following shall be addressed:

(1) quality control measures and assurance of radioisotope production of generator or cyclotron-produced agents;

(2) quality control measures and assurance of PET tomography and associated instrumentation;

(3) radiation protection and shielding;

(4) radioactive emission to the environment; and

(5) radioactive waste disposal.

History Note: *Authority G.S. 131E-177(1); 131E-183(b);*
Temporary Adoption Eff. September 1, 1993 for a period of 180 days or until the permanent rule becomes effective, whichever is sooner;
Eff. January 4, 1994;
Temporary Amendment Eff. January 1, 2002;
Temporary Amendment effective January 1, 2002 amends and replaces a permanent rulemaking originally proposed to be effective August 1, 2002;
Amended Eff. April 1, 2003;

Temporary Amendment Eff. February 1, 2006;
Amended Eff. November 1, 2006;
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